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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,042	04/22/2002	Nils Norman	PU-9925	5734

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AMERSHAM BIOSCIENCES  
PATENT DEPARTMENT  
800 CENTENNIAL AVENUE  
PISCATAWAY, NJ 08855

EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/018,042

Applicant(s)

NORRMAN, NILS

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
2. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.
  - I. Claims 1-10 drawn to a method of identifying one or more substances having affinity for a given target substance.
  - II. Claims 11-15 drawn to a library of different ligands.
3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.
4. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” It further defines “special technical feature” as “those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art.”

5. The technical feature that links all of the claims is library of different ligands. The groups lack unity because this technical feature is *known in the art* as disclosed by Dower et al. (US Pat. No. 5,708,153) (Date of Patent is **January 13, 1998**). This reference is described below.

6. Dower et al. (see entire document) disclose synthetic oligomer “ligand” libraries that incorporate multiple “identifier tags” for each “class” of particles (e.g., see Dower et al., column 7, lines 57-67 to column 8, lines 1-7; see especially figure 2 wherein tags are denoted by circles and classes of molecules are denoted by the separate containers). Dower et al. disclose apportioning the supports (carriers) among a plurality of reaction vessels (i.e., forming different “classes” of particles); exposing the supports in each reaction vessel to a first oligomer monomer and to a first identifier tag (reporter) monomer; pooling the supports; exposing the supports to a second oligomer monomer and to a second identifier tag monomer; exposing the supports to a second oligomer monomer and to a second identifier tag monomer (i.e., using split-mix technology). The identifier tag may be attached by means of a linker (physical or chemical attachment) that has an appropriate functional group at each end, one for the attachment to the support and the other for the attachment to the identifier tag (see column 7, lines 50-54). The identifier tag may be any recognizable feature such as microscopically distinguishable in shape, size, color, or optical density (see column 4, lines 24-36).

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7. Therefore, the technical feature linking the inventions of groups I-II does not constitute a species technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Groups I-II are different in that the special technical feature of Group I is drawn to a library of compounds. The special technical feature of Group II is drawn to a method for using/screening a library of compounds.

8. Accordingly, groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

9. Finally, see 37 CFR § 1.475 - Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage, cited in part below (especially sections (c) and (d)).

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- A product and a process specially adapted for the manufacture of said product;
- or
- A product and process of use of said product; or
- A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- A process and an apparatus or means specifically designed for carrying out the said process; or
- A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

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(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

10. Groups I-II represent product and process of using, respectively. However, the technical feature that links the claims (the tagged library) is known in the art, as set forth above. In addition, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the instant case, the product as claimed can be used in a materially different process e.g., to form additional libraries or for therapeutic purposes instead of for screening.

Thus, the instant claims lack unity of invention.

### *Species Election*

11. This application contains claims directed to more than one species of the generic invention for Groups I-II. These species are deemed to lack unity of invention because they are not so linked to form a single general inventive concept under PCT Rule 13.1.

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12. If applicant elects the invention of Group I applicant is required to elect from the following patentably distinct species. Claim 1 is generic. Applicant must elect one species from each subgroup below.

Subgroup 1: Species of particle class characterization (e.g., see claim 2)

Applicant must elect for the purposes of search a single species particle class characterization (e.g., size).

Subgroup 2: Species of particle sub-class characterization (e.g., see claim 3)

Applicant must elect, for the purposes of search, a single species of particle sub-class characterization (e.g., density, shape, color).

Subgroup 3: Species of substance marker (if present) (e.g., see claims 4-5)

Applicant must elect for the purposes of search a single species of substance marker (e.g., fluorescent moiety).

Subgroup 4: Species of identification method (e.g., see claim 8)

Applicant must elect, for the purposes of search, a single species of identification method (e.g., ocular inspection under microscope).

13. If applicant elects the invention of Group II applicant is required to elect from the following patentably distinct species. Claim 11 is generic. Applicant must elect one species from each subgroup below.

Subgroup 5: Species of first property (e.g., see claim 12)

Applicant must elect for the purposes of search a single species of first property (e.g., size).

Subgroup 6: Species of second property (e.g., see claim 13-15)

Applicant must elect, for the purposes of search, a single species of second property (e.g., density, shape, color).

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14. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

15. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; **and**
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or
- (b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

16. In the instant case, the library members do not have a common structure because the library members must be distinguished from each other based on their differences.

Consequently, the group as a whole does not share a common structure or a significant common structural element. Likewise, the method of identification employs different instrumentation.

For these reasons, election under these rules is proper and required.

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the



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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that a reply to this requirement *must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.* An argument that a claim is allowable or that all claims are generic is considered *nonresponsive* unless accompanied by an election.

19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, *applicant must indicate which are readable upon the elected species.* MPEP § 809.02(a).

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


22. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Jon D. Epperson, Ph.D.  
November 29, 2004

  
**ANDREW WANG**  
SUPERVISORY PATENT EXAMINER  
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